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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO				
09/867,570	05/31/2001	Ming-Hui Wei	CL000900CIP	8055				
25748	7590 01/24/2005		EXAM	INER				
	ENOMICS CORP.	LOCKARD, JON MCCLELLAND						
ATTN: WAY	-	E PRES, INTEL PROPERTY	ART UNIT	PAPER NUMBER				
C2-4#20			1647					
ROCKVILLE	, MD 20850		DATE MAILED: 01/24/2009	5				

Please find below and/or attached an Office communication concerning this application or proceeding.

- · · · · · · · · · · · · · · · · · · ·		Applicatio	n No.	Applicant(s)							
		09/867,570)	WEI ET AL.							
	Office Action Summary	Examiner		Art Unit							
		Jon M Lock	ard	1647							
Period fo	The MAILING DATE of this communication apport	pears on the	cover sheet with the c	orrespondence a	ddress						
A SH THE - External after - If the - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a repl or period for reply is specified above, the maximum statutory period or to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	136(a). In no ever ly within the statut will apply and will e, cause the applic	or, however, may a reply be time ory minimum of thirty (30) days expire SIX (6) MONTHS from the cation to become ABANDONEI	nely filed s will be considered time the mailing date of this D (35 U.S.C. § 133).							
Status											
1)⊠	Responsive to communication(s) filed on 23 S	September 20	<u>004</u> .								
2a)	This action is FINAL . 2b)⊠ This	s action is no	n-final.								
3)[Since this application is in condition for allowarclosed in accordance with the practice under E	, i			e merits is						
Dispositi	ion of Claims										
5)□ 6)⊠ 7)□	Claim(s) 4,8,9,12 and 24-29 is/are pending in 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) 4, 8-9, 12, and 24-29 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	wn from con	sideration.								
Applicati	ion Papers										
10)	The specification is objected to by the Examine The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Example 1.	cepted or b)[drawing(s) be ction is require	e held in abeyance. See d if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 C							
Priority (under 35 U.S.C. § 119										
a)(Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureasee the attached detailed Office action for a list	ts have beer ts have beer prity docume au (PCT Rule	received. received in Applications ats have been received 17.2(a)).	on No ed in this Nationa	ıl Stage						
2) Notice	the of References Cited (PTO-892) the of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	·)	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P	ate atent Application (P1	rO-152)						
	mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date <u>7/1/02, 9/23/04</u> .)	6) Other: <u>Sequence AL</u>		0-132)						

Application/Control Number: 09/867,570

Art Unit: 1647

DETAILED ACTION

Election/Restrictions

- 1. Applicant's election of Group III, claims 4-5, 8-11, and 22-23 drawn to nucleic acids of SEQ ID NOs:2 and 3, vectors and host cells comprising the same, and a method of recombinantly producing the polypeptide of SEQ ID NO:2, in the reply filed on 23 September 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 2. The restriction requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, And/Or Claims

3. Applicants' amendment filed on 23 September 2004 has been received and entered in full. Claims 1-3, 5-7, and 10-23 have been cancelled, claims 4 and 8-9 have been amended, and claims 24-29 have been added. Claims 4, 8-9, and 24-29 are currently pending.

Information Disclosure Statement

4. The Information Disclosure Statements (IDS) submitted on 01 July 2002 and 23 September 2004 have been considered by the Examiner. The BLAST results submitted on 23 September 2004 demonstrate that applicants are aware of proteins with identity/homology to the one claimed herein. However, as the BLAST results do not give sufficient identifying information, the Examiner cannot determine if said sequences constitute prior art.

Application/Control Number: 09/867,570

Art Unit: 1647

Claim Rejections - 35 USC § 101 and 35 USC §112

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Page 3

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 6. Claims 4, 8-9, and 24-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility. Novel biological molecules lack an established utility and must undergo extensive experimentation to determine an appropriate specific, substantial, and credible utility.
- The instant application discloses a nucleic acid set forth as SEQ ID NO:1 (transcript) and SEQ ID NO:3 (genomic) that encodes the protein set forth as SEQ ID NO:2, and vectors and host cells comprising the same. The specification asserts that SEQ ID NO:2 is a G protein coupled receptor (GPCR) that is related to the human Mas-related GPCR subfamily based on a high degree of homology to known GPCR sequences (See page 11, line 10-12; Figure 1). The Specification also discloses that the nucleic acid encoding SEQ ID NO:2 is expressed in human erythroleukemia cells and testis (See page 11, lines 19-20; Figure 1). The instant specification does not teach any physiologic ligands or functional characteristics of the GPCR set forth in SEQ ID NO:2 or encoded by the disclosed nucleic acid set forth in SEQ ID NOs:1 and 3. There is no

Application/Control Number: 09/867,570

Art Unit: 1647

well-established utility for a specific nucleic acid or amino acid sequence and the specification fails to disclose a specific and substantial utility for the claimed invention.

- 8. The specification asserts the following as patentable utilities for the claimed DNA (SEQ ID NOs:1 and 3) encoding the receptor protein of SEQ ID NO:2:
 - 1) as hybridization probes and PCR primers (pg 41, lines 7 and 13-19; pg 42, lines 13-24);
 - 2) recombinant production of the encoded protein (pg 41, lines 20-28);
 - 3) chromosome mapping (pg 41, line 29 pg 42, line 32);
 - 4) designing ribozymes (pg 42, lines 5-6);
 - 5) production of transgenic non-human animals (pg 42, lines 11-12);
 - 6) diagnostic kits (pg 42, line 28 pg 43, line 3);
 - 7) drug screening assays to identify compounds that modulate nucleic acid expression (pg 43, lines 4-5);
 - 8) methods of monitoring treatment (pg 44, lines 17-26);
 - 9) diagnostic assays (pg 44, line 27 pg 46, line 21);
 - 10) pharmacogenomics (pg 46, lines 22-28);
 - 11) antisense constructs (pg 47, lines 3-16);
 - 12) gene therapy (pg 47, lines 17-21);
 - 13) kits for nucleic acid detection (pg 47, line 22 pg 48, line 2); and
 - 14) useful in arrays (pg 48, line 5 pg 50, line 13).
- 9. These asserted utilities are neither specific nor substantial because they do not identify or reasonably confirm a "real world" context of use. The specification neither identifies the biological functions of the claimed protein and DNA, nor any diseases that are associated with the claimed molecules. Without any biological activity or link to a disease, such constitutes

further research to determine the properties of the claimed GPCR protein or partial peptides, which is insufficient to meet the requirement of 35 USC § 101.

Page 5

- 10. These activities and functions are conjectural and are based solely on the identification of the putative protein of SEO ID NO:2 as being a G-protein coupled receptor (GPCR). While it is credible that SEQ ID NO:2 is a GPCR, its identification as such is not sufficient to establish either a well known, or a specific, substantial and credible utility. There is no ligand identified that binds to it, no signaling pathway with which it is involved, and no disease or disorder correlated with the polypeptide. In Tables 3-5 it is disclosed that the nucleic acid is expressed in a variety of cell lines and tissues. The Specification discloses that the nucleic acid is expressed in human erythroleukemia cells and testis. The Instant Application has not provided sufficient experimental data to establish a nexus between the expression of the nucleic acid of SEQ ID NOs:1 and 3 and any disease or disorder. Since the instant specification does not disclose how to use the polypeptide of SEQ ID NO:2, a skilled artisan would not know how to use nucleic acids of SEO ID NO:1 and 3 that encode the polypeptide.
- The art teaches that the GPCR family is extremely diverse, and that function cannot be 11. predicted merely by identifying a protein as a GPCR. For example, Ji et al., in the Journal of Biological Chemistry 273(28): 17299-17302, teach that there have been nearly 2000 GPCR's reported, which are classifiable into 100 sub families according to sequence homology, ligand structure and receptor function. They further teach that different GPCR superfamily members are capable of sending signals via alternative signal molecules such as Jak2, phospholipase C, or protein kinase C, and that there are other seven transmembrane domain molecules that are not coupled to G proteins at all. Marchese et al. (Genomics 29:335), teach that IL-8 receptor,

Art Unit: 1647

neuropeptide Y receptor and Somatostatin receptors are all GPCR's. Thus, although the homology of the GPCR family, especially in the transmembrane domain regions, allows identification of such as GPCRs, mere homology and quantification of gene expression is not accepted by those of skill in the art as being predictive of function. Utility must be in readily available form. It is possible that, after further characterization, this protein might be found to have a patentable utility, in which case proteins would have a specific utility, or the protein might be found to be associated with a specific disease.

- 12. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a protein which has undetermined function or biological significance. Until some actual and specific activity or significance can be attributed to the protein identified in the specification as SEQ ID NO:2 or the polynucleotide encoding it (SEQ ID NOs:1 and 3), the claimed invention is incomplete.
- 13. Claims 4, 8-9, and 24-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and

Application/Control Number: 09/867,570 Page 7

Art Unit: 1647

credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make/use the claimed invention.

Summary

- 14. No claim is allowed.
- 15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- 16. Ahmad et al. (US Pat. No. 6,696,257) teach a nucleic acid (SEQ ID NO:4) that encodes a protein that shares 99% sequence identity with amino acid residues 16-337 of SEQ ID NO:2 of the Instant Application (See attached sequence alignment).
- 17. Chen et al. (US Application No. US20020193584 A1) teach a nucleic acid (SEQ ID NO:19) that encodes a protein that shares 100% sequence identity with amino acid residues 16-337 of SEQ ID NO:2 of the Instant Application (See attached sequence alignment).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard**, **Ph.D.** whose telephone number is (571) 272-2717. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, **Ph.D.** can be reached on (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JML January 10, 2005

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PRIMARY FXAMINER

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CURRENT FILING DATE: 1999-03-03
NUMBER OF SEQ ID NOS: 22
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APPLICANT: Lembo, Paola
APPLICANT: O'Donnell, Dajan
APPLICANT: Shi-Hsiang, Shen
TITLE OF INVENTION: G Protein-Coupled Receptors from the Rat and Human
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RESUM 2
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; Patent No. 6696257
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; APPLICANT: Ahmad, Sultan
; APPLICANT: Parrville, Denis
; APPLICANT: FOrtin, Yves
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APPLICANT: O'Donnell, Dajan
APPLICANT: Shi-Hsiang, Shen
ITILS OF INVENTION: G PROTEIN-Coupled Receptors fro
PALE REFERENCE: 81823/268117
CURRENT APPLICATION NUMBER: US/09/254,227A
CURRENT FILING DATE: 1999-03-03
NUMBER OF SEQ ID NOS: 22
SOFTWARE: Patentin version 3.0
SEQ IN NO 6
LENGTH: 969
TYPE DAA
ORGANISM: Homo sapiens
US-09-254/227A-6
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Pred. No.:
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CURRENT APPLICATION NUMBER: US/09/995,225
CURRENT PILING DATE: 2001-11-26
PRIOR FILING DATE: 1998-10-13
PRIOR APPLICATION NUMBER: PCT/US99/23938
PRIOR APPLICATION NUMBER: 60/253,404
PRIOR PILING DATE: 1998-10-13
PRIOR APPLICATION NUMBER: 60/253,404
PRIOR PILING DATE: 2000-11-27
PRIOR APPLICATION NUMBER: 60/255,366
PRIOR FILING DATE: 2000-12-12
PRIOR APPLICATION NUMBER: 60/270,286
PRIOR FILING DATE: 2001-02-20
PRIOR PILING DATE: 2001-02-26
PRIOR FILING DATE: 2001-02-26
PRIOR PILING DATE: 2001-02-20
PRIOR APPLICATION NUMBER: 60/282,032
PRIOR FILING DATE: 2001-04-06
PRIOR FILING DATE: 2001-04-06
PRIOR PILING DATE: 2001-04-06
PRIOR PILING DATE: 2001-04-06
PRIOR PILING DATE: 2001-04-06
PRIOR APPLICATION NUMBER: 60/282,356
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US-09-995-225-19
; Sequence 19, Application US/09995225
; Publication No. US20020193584A1
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APPLICANT: Chu, Zhi Liang
APPLICANT: Dang, Huong T.
APPLICANT: Lowitz, Kevin
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TYPE: DNA
ORGANISM: Artificial Sequence
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Lowitz, Kevin P.
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GENERAL (NFORMATION: Chen, Ruoping
APPLICANT: Chen, Ruoping
APPLICANT: Chen, Ruoping
APPLICANT: Chu, Zai Liang
APPLICANT: Dang, Huong T.
APPLICANT: Lowitz, Kevin P.
APPLICANT: Lowitz, Kevin P.
APPLICANT: Lowitz, Kevin P.
APPLICANT: Picke, Cameron
ITILE OF INVENTION: Endogenous And No. US20030139588A9-Endogenous Versions of H.
ITILE OF INVENTION: Receptors
FILIE REFERENCE: (AREN-0308
CURRENT APPLICATION NUMBER: US/09/995,225
CURRENT APPLICATION NUMBER: 09/170,496
PRIOR APPLICATION NUMBER: 09/170,496
PRIOR FILING DATE: 1998-10-13
PRIOR APPLICATION NUMBER: PCT/US99/23938
PRIOR FILING DATE: 1998-10-13
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Sequence 19, Application US/09995225

; Publication No. US20030139588A9

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PRIOR FILING DATE: 2000-11-27
PRIOR APPLICATION NUMBER: 60/255,366
PRIOR FILING DATE: 2001-02-12
PRIOR APPLICATION NUMBER: 60/270,286
PRIOR PILING DATE: 2001-02-06
PRIOR PILING DATE: 2001-04-06
PRIOR PILING DATE: 2001-04-06
PRIOR PILING DATE: 2001-04-06
PRIOR APPLICATION NUMBER: 60/282,358
PRIOR PILING DATE: 2001-04-06
PRIOR APPLICATION NUMBER: 60/282,358
PRIOR PILING DATE: 2001-04-06
PRIOR APPLICATION NUMBER: 60/282,356
PRIOR APPLICATION NUMBER: 60/290,917
PRIOR PILING DATE: 2001-05-14
PRIOR PILING DATE: 2001-05-14
PRIOR PILING DATE: 2001-07-31
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FEATURE:
OTHER INFORMATION: NO
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                                                                     ValMetCysValLeuLeuTrpAlaLeuSerLeuLeuArgSeAlleLeuGluTrpMetPhe 175
                                                                                                                                                    CysLeuSerIleLeuTrpProIleTrpTyrHisCysA
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